HEWLETT-PACKARD COMPANY
Intellectual Property Administration
P.O. Box 272400
Fort Collins, Colorado 80527-2400

PATENT APPLICATION

ATTORNEY DOCKET NO. 200316700-1

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Iddys D. Figueroa et al.	**Confirmation No.:** 8624
Application No.: 10/825,870	**Examiner:** Cachet I. Sellman
Filing Date: April 16, 2004	**Group Art Unit:** 1792

Title: A System and a Method for Producing Layered Oral Dosage Forms

Mail Stop Appeal Brief-Patents
Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on November 4, 2009 .

☒ The fee for filing this Appeal Brief is $540.00 (37 CFR 41.20).

☐ No Additional Fee Required.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☐ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $130	☐ 2nd Month $490	☐ 3rd Month $1110	☐ 4th Month $1730

☐ The extension fee has already been filed in this application.

☒ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 540 . At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

Respectfully submitted,
Iddys D. Figueroa et al.

By: /Steven L. Nichols/
Steven L. Nichols
Attorney/Agent for Applicant(s)
Reg No. : 40,326
Date : January 4, 2010
Telephone : 801-572-8066

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APPEAL BRIEF

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Sir:

This is an Appeal Brief under Rule 41.37 appealing the decision of the Primary Examiner dated August 4, 2009 (the "final Office Action"). Each of the topics required by Rule 41.37 is presented herewith and is labeled appropriately.

I. Real Party in Interest

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 11445 Compaq Center Dr. W. Houston, TX 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. Related Appeals and Interferences

There are no appeals or interferences related to the present application of which the Appellant is aware.

III. Status of Claims

Claims 22-53 and 63-79 were withdrawn from consideration under the imposition of a previous Restriction Requirement and cancelled without prejudice or disclaimer. Subsequently, claims 2, 6, 55, 59, 61 and 99 were also cancelled without prejudice or disclaimer

In the current Office Action, claims 54, 56-58, 60, 62 and 80-91 are allowed and are not at issue in the present appeal.

Claims 1, 3-5, 7-21, 92-98 and 100 are pending in the application and stand finally rejected. Accordingly, Appellant takes this appeal from the final rejection of claims 1, 3-5, 7-21, 92-98 and 100, which claims are presented in the Appendix.

IV. Status of Amendments

No amendments have been filed subsequent to the final Office Action of August 4, 2009, from which Appellant takes this appeal.

V. Summary of Claimed Subject Matter

Appellant's specification describes and claims systems and methods for producing a layered polymer or gelatin based oral dosage form. More specifically, a jettable pharmaceutical solution is jetted onto an edible polymer or gelatin based structure to form an oral dosage form. The jettable pharmaceutical solution may include any number of solvents to further modify the release rate of an oral drug formulation. (*Appellant's specification, paragraph 0016*).

Claim 1, which is the only independent claim still at issue in this appeal, recites the follow subject matter.

A method for producing an oral medication comprising:

with an inkjet dispenser (Fig. 1), dispensing a structural material (300) (*Appellant's specification, Fig. 4 and paragraph 0042)*, said structural material including one of a polymer or a gelatin (*Appellant's specification, paragraph 0053*) ;

curing said structural material (310) (*Appellant's specification, paragraph 0042*);

with said inkjet dispenser (Fig. 1), dispensing a jettable pharmaceutical solution (330) onto said cured structural material (*Appellant's specification, Fig. 5 and paragraph 0042*); and

dispensing alternating layers (*Appellant's specification, paragraph 0027*) of said structural material and said pharmaceutical solution (340) (*Appellant's specification, paragraph 0042*).

VI. Grounds of Rejection to be Reviewed on Appeal

The final Office Action raised the following grounds of rejection.

(1) Claims 1, 3-5, 7-21, 92-98 and 100 were rejected under 35 U.S.C. §101, first paragraph, as allegedly failing to comply with the written description requirement of that paragraph.

According, Appellant hereby requests review of each of these grounds of rejection in the present appeal.

VII. Argument

(1) Claims 1, 3-5, 7-21, 92-98 and 100 comply with 35 U.S.C. §101, first paragraph:

For ease of reference, claim 1 recites:

> A method for producing an oral medication comprising:
> with an inkjet dispenser, dispensing a structural material, said structural material including one of a polymer or a gelatin;
> curing said structural material;
> with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material; and
> dispensing alternating layers of said structural material and said pharmaceutical solution.

The sole issue raised in the final Office Action is a rejection of claims 1, 3-5, 7-21, 92-98 and 100 under 35 U.S.C. § 112, first paragraph. According to the Action, these claims fail to satisfy the written description requirement of § 112, first paragraph.

> In independent claim 1, the Appellants claim using the same inkjet dispenser to dispense the structural material and the jettable pharmaceutical solution. However, support for this limitation is not provided in the specification. The specification (see paragraph 0019, 0021, 0022, 0040 and Figures 1 and 4-5) teaches using a plurality of ink jet dispensers (150, 150') to dispense the structural material and jettable pharmaceutical solution.

(final Office Action, pp. 2-3).

Appellant respectfully disagrees for the following reasons.

With regard to the "written description" requirement of § 112, first paragraph, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, Appellant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). According to MPEP § 2163.02, an "Appellant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas

that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

With these standards in mind, Appellant refers to Fig. 1 of the instant application. Fig. 1 is reproduced below for ease of reference.

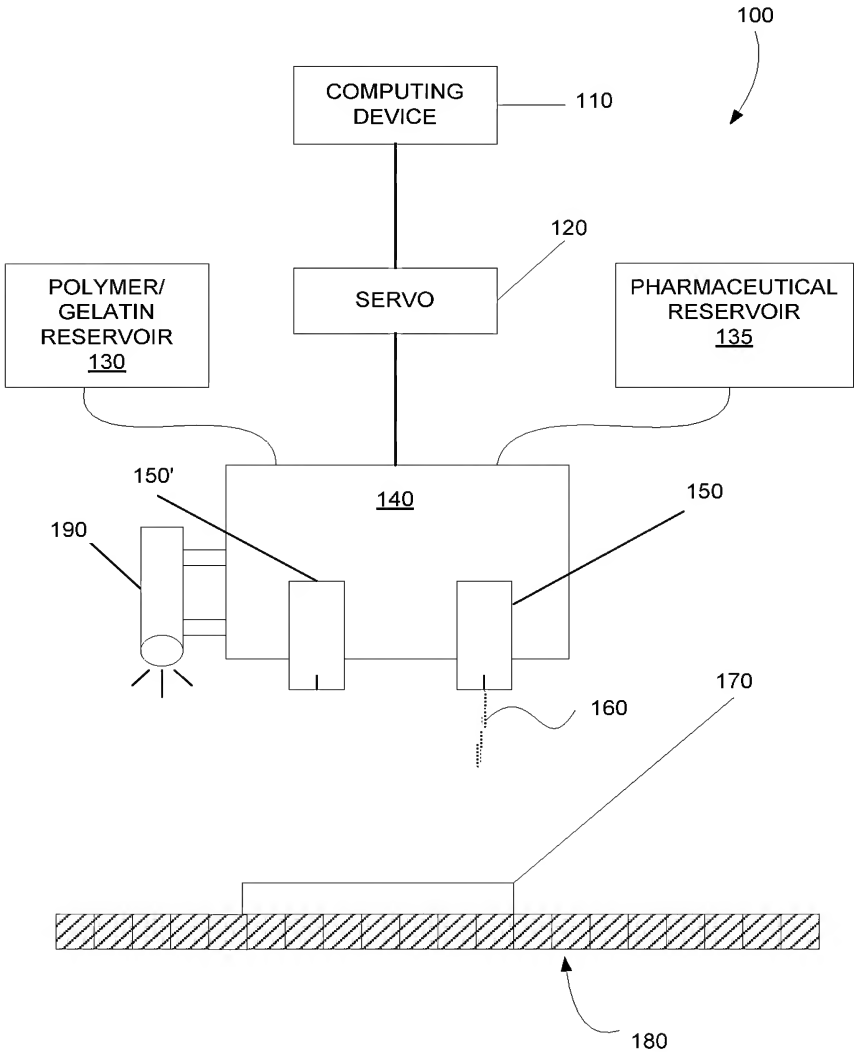

Fig. 1

Fig. 1 illustrates a single "system may be used to form a layered polymer/gelating oral does." (Appellant's specification, paragraph 0006). The illustrated system includes a single computing device (110) and servo (120) driving a carriage (140) which is connected to both a

polymer/gelatin reservoir (130) and a pharmaceutical reservoir (135). The carriage (140) includes two inkjet dispensing units (150', 150) for respectively dispensing the polymer/gelatin and the pharmaceutical, and an energy unit (190) for curing the polymer/gelatin as a structural material after dispensing. Referring specifically to the language of Appellant's specification, paragraph 0020 reads as follows. "The computing device (110) that is controllably coupled to the servo mechanism (120), as shown in Figure 1, controls the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution (160)." (Appellant's specification, paragraph 0020).

Fig. 4 illustrates the unit of Fig. 1 dispensing the polymer/gelatin and curing the same with the energy source (190).

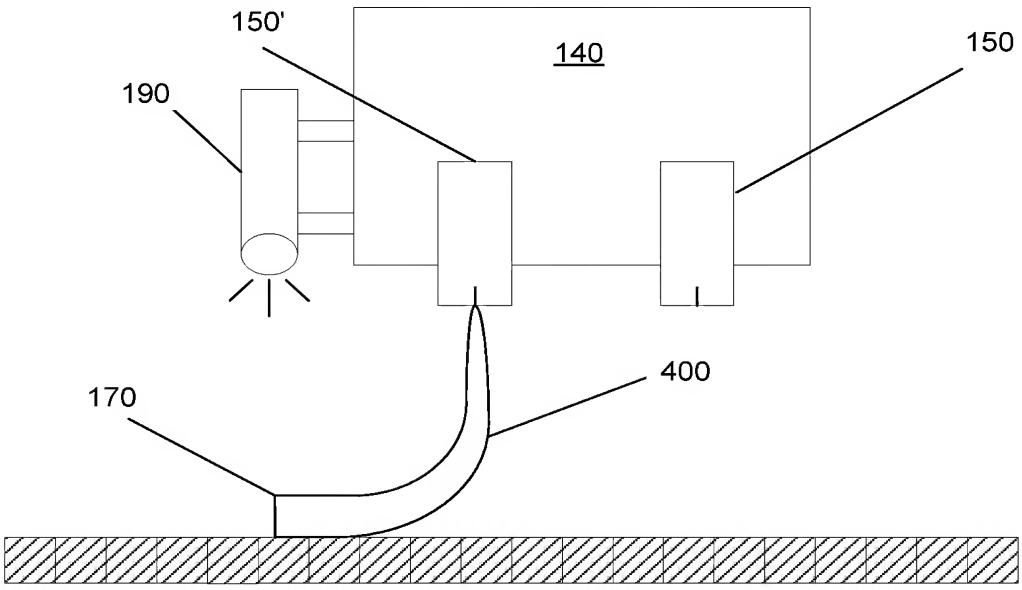

Fig. 4

Fig. 5 illustrates the unit of Fig. 1 dispensing the pharmaceutical from the corresponding pharmaceutical reservoir.

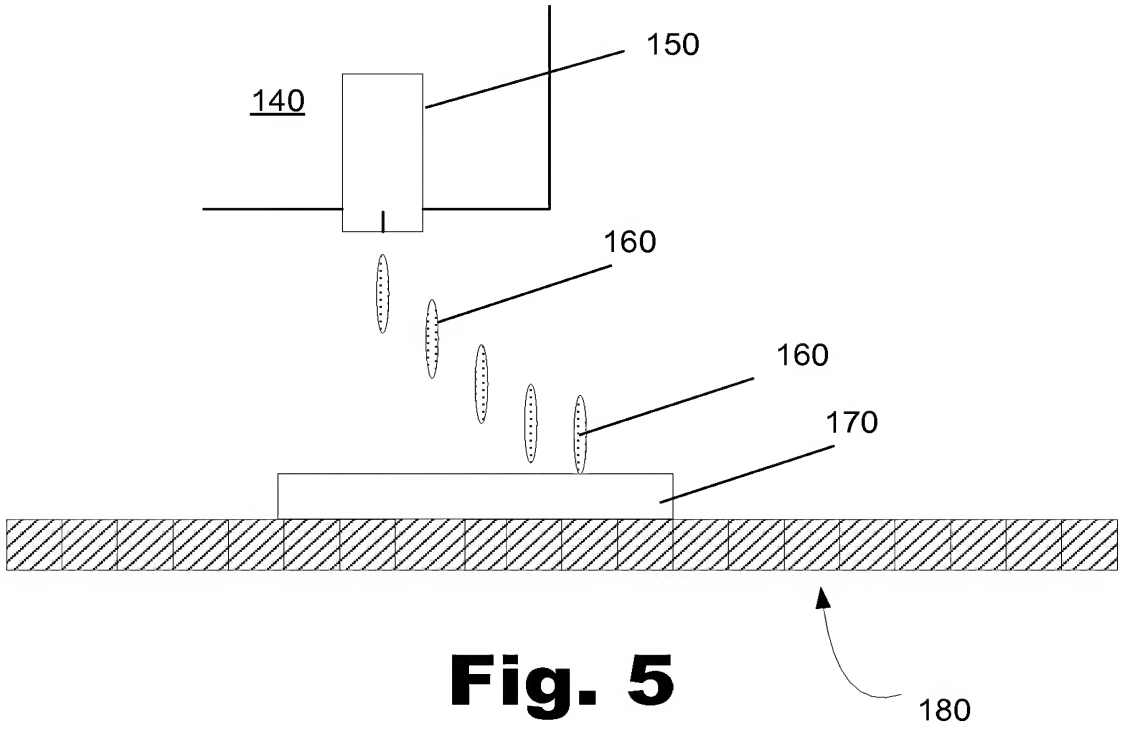

Fig. 5

Thus, the inkjet dispenser system of Fig. 1 includes the computing device (110), servo mechanism (120), the carriage (140) and the two inkjet heads (150, 150') and respective reservoirs of structural material (130) and pharmaceutical (135). Taken collectively, these components comprise an inkjet dispenser system that provides for "the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution (160)." (Appellant's specification, paragraphs 0006 and 0020).

Appellant believes that Figs. 1, 4 and 5, along with the supporting text from the specification, provide an adequate written description to support the recited method of claim 1. Given these figures and description, one of skill in the art would have clearly understood that Appellant was in possession of a method comprising "with an inkjet dispenser,

dispensing a structural material, said structural material including one of a polymer or a gelatin; curing said structural material; with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material; and dispensing alternating layers of said structural material and said pharmaceutical solution." (Claim 1).

The objection of the final Office Action is based on an unreasonable and unfair construction of the language of claim 1. The final Office Action appears to want claim 1 construed as requiring only a single inkjet head with both the structural material and the pharmaceutical passing sequentially through precisely the same nozzles of one single inkjet head. Hence the following argument from the final Office Action.

> In independent claim 1, the Appellants claim using the same inkjet dispenser to dispense the structural material and the jettable pharmaceutical solution. However, support for this limitation is not provided in the specification. The specification (see paragraph 0019, 0021, 0022, 0040 and Figures 1 and 4-5) teaches using a plurality of ink jet dispensers (150, 150') to dispense the structural material and jettable pharmaceutical solution. Specifically the Appellant teaches dispensing the structural material using dispenser (150') and the jettable solution using (150) see Figure 1. There is no indication or suggestion in the specification of the use of one ink jet dispenser to dispense the structural material as well as the jettable solution. The specification teaches using a movable carriage holding the two dispensers thereon. Therefore the specification does not provide support for one dispenser to dispense both structural material and jettable solution.

(final Office Action, pp. 2-3).

Thus, if claim 1 is construed as requiring that both the structural material and pharmaceutical are dispensed through exactly the same nozzles of a single inkjet head, such a limiting conception of claim 1 is not supported with a written description in the specification and the rejection under §101 is likely proper. Appellant, however, rejects any such unreasonably narrow construction of claim 1.

Rather, Appellant contends that the "inkjet dispenser" of claim 1 can refer, for example, to the system of claim 1 as a whole, which dispenses both structural material and pharmaceutical solution from respective, individual inkjet heads/dispensers on a single

carriage controlled by a single controller. This is supported by Appellant's specification, which expressly describes a single, unitary "system that may be used to form a layered polymer/gelatin oral dose." (Appellant's specification, paragraph 0006).

Moreover, the final Office Action completely forgets that claims are to be construed from the perspective of one skilled in the art. If the unreasonable construction of claim 1 advanced by the final Office Action were adopted, a host of unnecessary issues are raised. Specifically, if precisely the same nozzles of an inkjet head are used to dispense first a structural material and then a pharmaceutical solution, as recited in claim 1, there must then be some mechanism for discontinuing the supply of structural material to the head following deposition of the structural material, some mechanism for emptying and cleaning the head of the structural material, and then some mechanism for connecting the head to the supply of pharmaceutical solution and priming the head with that solution. One of skill in the art would appreciate that claim 1 is not attempting to claim or refer to any such cumbersome and unrealistic embodiment. Rather, one of skill in the art would readily appreciate that multiple heads are commonly added to a single dispensing unit to dispense different materials, for example, differently colored inks, without implicating the host of issues mentioned above associated with running different materials through exactly the same dispensing head. In short, if claim 1 is considered, as it must be, from the perspective of one skilled in the art, the construction of claim 1 on which the final Office Action bases its rejection under § 101 appears utterly unreasonable.

Consequently, the "ink jet dispenser" recited in claim 1 may refer to the carriage (140) and the two inkjet heads (150, 150') and other components of Fig. 1 collectively as an "inkjet dispenser." Such a construction would be clear to one of ordinary skill in the art for the reasons given above and supported by Appellant's specification at paragraph 0020.

Paragraph 0020 reads as follows. "The computing device (110) that is controllably coupled to the servo mechanism (120), as shown in Figure 1, controls the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution (160)." (Appellant's specification, paragraph 0020).

Thus, the inkjet dispensing system comprising the computing device (110), servo mechanism (120) and the carriage (140) and the two inkjet heads (150, 150') comprise a single inkjet dispensing unit that provides for "the selective deposition of both a structural material used to form the edible structure (170) as well as a jettable pharmaceutical solution (160)." (*Id.*). There is no basis for construing claim 1 so narrowly as to require that both the structural material and the pharmaceutical solution are dispensed through exactly the same nozzles of a single inkjet head. To the extent that the rejection under § 112, first paragraph, is based on such a narrow construction of the claim language, Appellant respectfully rejects any such limiting construction of the claims.

In conclusion, as demonstrated above, Appellant's specification clearly provides a written description demonstrating that Appellant had possession of the method recited in claim 1 at the time the application was filed. Therefore, the rejection of Appellant's claims under § 101 should not be sustained.

In view of the foregoing, it is submitted that the final rejection of the pending claims is improper and should not be sustained. Therefore, a reversal of the Rejection of August 4, 2009 is respectfully requested.

Respectfully submitted,

DATE: January 4, 2010

/Steven L. Nichols/
Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095
(801) 572-8066
(801) 572-7666 (fax)

VIII. CLAIMS APPENDIX

1. (previously presented)A method for producing an oral medication comprising:

with an inkjet dispenser, dispensing a structural material, said structural material including one of a polymer or a gelatin;

curing said structural material;

with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material; and

dispensing alternating layers of said structural material and said pharmaceutical solution.

2. (cancelled)

3. (previously presented)The method of claim 1, wherein said inkjet material dispenser comprises one of a thermally actuated inkjet dispenser, a mechanically actuated inkjet dispenser, an electro-statically actuated inkjet dispenser, a magnetically actuated dispenser, a piezo-electrically actuated inkjet dispenser, or a continuous inkjet dispenser.

4. (previously presented)The method of claim 1, wherein said dispensing said structural material comprises:

selectively jetting said structural material from said inkjet dispenser;

said inkjet dispenser comprising one of a thermally actuated inkjet dispenser, a mechanically actuated inkjet dispenser, an electro-statically actuated inkjet dispenser, a

magnetically actuated dispenser, a piezo-electrically actuated inkjet dispenser, or a continuous inkjet dispenser.

5. (original) The method of claim 1, wherein said step of curing said structural material comprises vacuum drying or thermally drying said structural material.

6. (cancelled)

7. (previously presented)The method of claim 1, further comprising curing said alternating layers of said structural material prior to dispensing said alternating layers of said pharmaceutical solution.

8. (original) The method of claim 1, wherein said structural material comprises one of a maltotriose-based pullulan, a gelatin, a polyvinyl alcohol (PVA), a PVA-polyethylene oxide, a PVA-vinylamine, a polyvinyl pyrrolidone (PVP), a PVP-polyvinyl acetate, a cationic PVP, a crosslinked PVP, a sorbitol, a wheat gluten, a seaweed, a cellulose, a methyl cellulose, a hydroxypropyl methyl cellulose (HPMC), a poly vinyl methyl ether (PVME), a PVME- propylene glycol monomethyl ether acetate (PMA), a poly (2-ethyl 2-oxazoline), or a pectin.

9. (previously presented)The method of claim 1, wherein said dispensing a structural material further comprises dispensing a plurality of selective quantities of said structural material onto discrete locations of a substrate.

10. (original) The method of claim 1, further comprising forming said jettable pharmaceutical solution.

11. (original) The method of claim 10, wherein forming a jettable pharmaceutical solution comprises:

presenting an oral drug component; and

combining an edible jettable vehicle component with said oral drug component.

12. (previously presented)The method of claim 11, wherein said oral drug component comprises one of an ace inhibitor, an antianxiety medication, an antibiotic, a antihypertensive medication, an antiviral medication, a blood glucose regulator, an Alzheimer-type dementia medication, an anorexiant, a central nervous system stimulant, an antidiuretic, an antidote, an antihistamine, an antipsychotic medication, an antimanic medication, a beta blocker, a calcium channel blocker, a contraceptive, a dermatologic, a diuretic, an estrogen, a progestin, an entrapyramidal movement disorder medication, a sedative, or a hypnotic medication.

13. (original) The method of claim 12, wherein said oral drug component further comprises one of triazolam, felodipine, trandolapril, pergolide, rivastigmine tartrate, sibutramine hydrochloride, desmopressin acetate, flumazenil, desloratadine, risperidone, carvedilol, isradipine, norgestimate, methoxsalen, metolazone, estradiol, estrogens, conjugated estrogent, esterified cabergoline, zaleplon, or zolpidem tartrate.

14. (original) The method of claim 11, wherein said jettable vehicle component comprises a solvent.

15. (original) The method of claim 14, wherein said solvent is configured to dissolve said oral drug component.

16. (original) The method of claim 15, wherein said solvent is configured to partially dissolve said structural material.

17. (original) The method of claim 16, wherein said solvent comprises one of a water and methanol acetonitrile solvent, an acetone and dimethylsulfoxide (DMSO) solvent, a DMSO and methanol solvent, a DMSO and potassium chloride (KCl) and water solvent, a KCl and water solvent, water, a t-butanol and water solvent, an ethanol and water solvent, a methanol and water solvent, an I-propanol and water solvent, an n-propanol and water solvent, an NaCl and water solvent, a piperazine solvent, a diethylene-diamine solvent, a formamide solvent, a dimethylformamide (DMF), a DMSO solvent, a hexamethylphosphoric triamide solvent, a glycols solvent, a glycerol solvent, a dichloromethane solvent, a polar solvent, an acetone/water solvent, a dioxane solvent, an aqueous alkali solvent, a methanol/methylene chloride solvent, an N-ethylpyridinium chloride and DMF solvent, a chloroform solvent, an acetone solvent, a pyridine solvent, an ester solvent, a cyclohexanone solvent, an N-ethylpyridinium chloride and pyridine solvent, a diluted acid solvent, or an ethylene diamine solvent.

18. (original) The method of claim 15, wherein said solvent is configured to not dissolve said structural material.

19. (original) The method of claim 18, wherein said solvent comprises one of an organic solvent, a hydrocarbon solvent, a chlorinated hydrocarbon solvent, a lower alcohol solvent, a tetrahydrofuran solvent, a ketone solvent, a carboxylic acid solvent, an ester solvent, salt solvent, a water solvent, a diethyl ether solvent, a methylene chloride solvent, an ethanol solvent, an aliphatic hydrocarbon solvent, a diluted aqueous alkali solvent, or an alcohol solvent.

20. (original) The method of claim 14, wherein said jettable vehicle component further comprises one of a humectant, a surfactant, a colorant, a drier, a thinner, a wax, a lubricant, a reducing oil, a solvent, a body gum, a binding varnish, an antioxidant, an anti-skinning agent, a resin, or a binder.

21. (previously presented)The method of claim 1, wherein said dispensing alternating layers of said structural material and said pharmaceutical solution is configured to control a release rate of said pharmaceutical solution.

22-53. (cancelled)

54. (allowed)

55. (cancelled)

56-58. (allowed)

59. (cancelled)

60. (allowed)

61. (cancelled)

62. (allowed)

63-79. (cancelled)

80-91. (allowed)

92. (previously presented)The method of claim 1, wherein said pharmaceutical solution comprises a solvent that dissolves said pharmaceutical solution into said structural material, said method further comprising controlling a quantity of said solvent to control release characteristics of said pharmaceutical solution.

93. (previously presented)The method of claim 1, wherein said pharmaceutical solution comprises a solvent that dissolves said pharmaceutical solution into said structural material, said method further comprising varying said solvent to control release characteristics of said pharmaceutical solution.

94. (previously presented)The method of claim 1, wherein dispensing said structural material comprises depositing a first layer of structural material onto a non-adhesive substrate.

95. (previously presented)The method of claim 94, wherein said non-adhesive substrate comprises glass or polytetrafluorethylene.

96. (previously presented)The method of claim 1, wherein dispensing said structural material comprises depositing a first layer of structural material onto an edible substrate.

97. (previously presented)The method of claim 96, wherein said edible substrate comprises a sheet of edible polymer.

98. (previously presented)The method of claim 97, wherein said edible polymer comprises pullulan, polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), calcium alginate, gelatin, or a combination thereof.

99. (cancelled)

100. (previously presented)The method of claim 1, in which said inkjet dispenser comprises a moveable carriage supporting both a first inkjet material dispenser for dispensing said structural material and a second inkjet material dispenser for dispensing said

pharmaceutical solution, said method further comprising controlling said first and second inkjet material dispensers with a computing device to selectively deposit both said structural material and pharmaceutical solution.

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None